Automated Commercial Environment/ International Trade Data System (ACE/ITDS) Frequently Asked Questions

1) What is FDA's role in the import process?

FDA plays a major role in the importing of goods into the United States. Due to the large volume of products under FDA jurisdiction, as well as the size of its workforce, FDA is the largest partner government agency that works with U.S. Customs and Border Protection (CBP). In FY14, FDA received more than twenty percent of imported goods in the United States consisting of more 34 million product lines of FDA-regulated commodities. Each of these product lines is electronically screened to determine admissibility. FDA's statutory authority to make admissibility determinations stems primarily from Section 801 of the Federal Food, Drug and Cosmetic Act, Title 21, United States Code, Section 381, which directs FDA to make import admissibility determinations based on compliance with the Act. FDA relies on a cooperative arrangement with CBP in carrying out its duties at the border.

When an FDA-regulated product is offered for import into U.S. commerce, CBP, through an information technology interface, electronically notifies FDA and FDA electronically screens each product line. FDA's PREDICT application provides a risk score for the product line that can either recommend the product to proceed into commerce or provide information to staff so other actions can be taken. FDA staff review information and determine whether a field exam or sampling is necessary, if more information should be requested, or if the entry should be released or subject to refusal. In conjunction with this process, FDA manages a system of import alerts and other guidance to provide direction to field staff in determining whether imported product lines have the appearance of a violation and warrant refusal, unless and until the importer demonstrates that the product is in compliance.

2) What exactly is ACE/ITDS?

The Automated Commercial Environment or ACE is the new commercial database system of the U.S. Customs and Border Protection (CBP). ACE is in the process of replacing the current commercial database, the Automated Commercial System, also known as ACS. The purpose of ACE is to streamline business processes, to facilitate growth in trade, to ensure cargo security, to provide better means to combat threats, and to foster participation in global commerce, while ensuring compliance with U.S. laws and regulations.

The International Trade Data System or ITDS will provide a "single window" for submitting trade information to all of the federal agencies with border responsibilities, generally referred to as Participating Government Agencies or PGAs. ITDS is not a separate computer system, but a set of functions that involve the systems and targeting of multiple agencies through ACE. The goal of ITDS is to have a single filing to replace multiple filings to multiple agencies under the current system and to distribute transaction data to the appropriate agencies, thereby eliminating redundant reporting and providing agencies with real-time access to relevant information for processing capability. The SAFE Port of Act provided a statutory direction by requiring the Secretary of the Treasury to oversee an interagency initiative to establish a single portal system to electronically collect and distribute import and export data required by federal agencies that license or clear the import or export of goods.

3) Why is this happening now?

On February 19, 2014, President Obama issued Executive Order 13569 to streamline export and import processes. Among other things, the Executive Order seeks to require the completion of the International Trade Data System (ITDS) by December 2016, to allow businesses to electronically transmit import and export data through a "single-window" for all federal agencies. This new system is intended to speed up the shipment of American-made goods overseas, help expedite imported products, eliminate duplicative and burdensome paperwork, and make processes more efficient.

The Executive Order also created an intergovernmental group, the Border Interagency Executive Council, to oversee the implementation of the Executive Order. That governing body has determined the deadline for entering all commodities into ACE to be February 28, 2016.

4) Why does FDA intend to require the submission of data elements in the future?

The dramatic expansion in the volume of imported products under FDA jurisdiction has strained agency resources and the ability to clear imports expeditiously. Business models also increasingly expect and require clearance in shorter time frames. Effective electronic screening provides the critical path for meeting these rising expectations. FDA needs such data for admissibility decisions. In order to do that job efficiently, FDA needs the data in electronic form. Admissibility decisions rely upon information to reliably indicate what a product is, where it was manufactured, grown or processed, if applicable, whether the agency has approved its use in the United States, and whether it meets other applicable regulatory requirements. Our own review has shown that poor data quality in the form of missing or inaccurate codes for FDA elements has significantly impeded the agency's progress in relying on electronic screening. Providing data at the initial stage of the process allows that to be validated and processed quickly. Where data is provided in this way and the product is compliant, FDA very often can admit the product into commerce in a few minutes. In contrast, where this information is not provided or it does not reflect information that manufacturers previously provided in FDA systems, clearance can take hours or even days. Given the volume, the cumulative effect of such delays makes an approach where the submission of key information is optional non-sustainable.

5) What data should be submitted?

FDA regulates numerous types of products, and the requirements are not necessarily the same. FDA will determine whether to admit an imported product under its jurisdiction based on whether there is an appearance that its shipment in interstate commerce would violate the Federal Food, Drug, and Cosmetic Act. The appearance of a violation may involve adulteration, misbranding, the lack of required approval, or other violations. Simply put, FDA needs to have some basic information to determine whether products meet applicable safety and efficacy standards or otherwise comply with the law. The data elements are identified and defined in the FDA supplemental guide available on the CBP website.